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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,964	07/08/2003	Hector F. DeLuca	1256-00777	8876
26753 7590 09/01/2010 ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202				
EXAMINER				
MCMILLIAN, KARA RENTIA				
ART UNIT		PAPER NUMBER		
1627				
MAIL DATE		DELIVERY MODE		
09/01/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,964

Applicant(s)

DELUCA ET AL.

Examiner

KARA R. MCMILLIAN

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 23-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 12, 2010 has been entered.

Response to Amendment/ Arguments

No amendments to the claims were made. Claims 1-21 and 23-39 were previously withdrawn. Claim 22 is presented for examination

Applicant's arguments filed July 12, 2010 have been fully considered but they are not persuasive. Applicants disagree with the Examiners position that it is clear from the disclosure of Deluca et al. that hydrogen is the preferred substituent of Y₁, Y₂, R₆ and R₈ since in both Schemes I and II in columns 21-26 of Deluca et al. the end products are exemplified with hydrogen being the substituent of Y₁, Y₂, R₆ and R₈. Applicants argue that the fact that the Scheme shows an end product with hydrogen for Y₁, Y₂, R₆ and R₈ does not mean that hydrogen is the preferred substituent rather in order to obtain the compounds claimed, hydrogen had to be inserted. Applicants further provide evidence that compounds disclosed as the final step in a synthesis scheme is not necessarily the

preferred compound, rather it is the compound that is converted into the desired compounds.

This argument is found not persuasive because the compounds in Deluca et al disclosed as the end products of both Schemes I and II in columns 21-26 are also the specific compounds claimed in claims 12 and 13 of DeLuca et al. and having hydrogen as the substituent of Y₁, Y₂, R₆ and R₈. Thus as previously argued, it is clear from the disclosure of Deluca et al. and the claims of Deluca et al. that hydrogen is the preferred substituent of Y₁, Y₂, R₆ and R₈. Thus since hydrogen is the preferred substituent of Y₁, Y₂, R₆ and R₈ and claim 8 of Deluca et al. specifically claims the preferred R side chain, Applicants claimed compound of claim 22 is anticipated since one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula.

Thus, for reasons of record and for the reasons presented above, the previous rejection under 35 USC 102 is hereby maintained and reproduced below. This action is made Non-FINAL.

Claim Rejections - 35 USC § 102

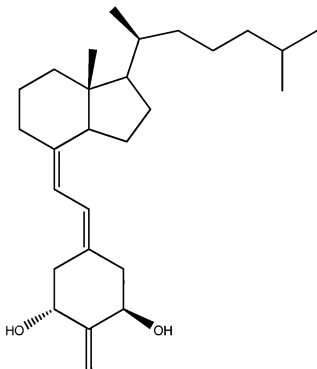
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

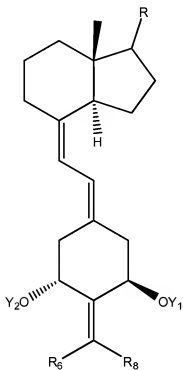
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Deluca et al. U.S. Patent No. 5,843,928 (provided on IDS).

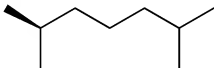
Claim 22 of the instant application claims the compound (20S)-1 α -hydroxy-2-methylene-19-nor-vitamin D₃ having the formula:



Deluca et al. claim a novel class of vitamin D related compounds, namely, the 2-alkylidene-19-nor-vitamin D derivatives (see abstract). Claim 1 of Deluca et al. claims a compound having the formula:



where Y_1 and Y_2 are selected from the group consisting of hydrogen and a hydroxyl-protecting group and R_6 and R_8 are selected from hydrogen, alkyl, hydroxyalkyl and fluoroalkyl, or when taken together represent the group $-(CH_2)_x$, where x is an integer from 2 to 5. Claim 8 of Deluca et al. claims the compound of claim 1 where R is a side chain of the formula:



Applicant's claimed compound is exemplified in claim 8 of Deluca et al. when Y_1 , Y_2 , R_6 and R_8 are all hydrogen. The compound of instant claim 22 is anticipated since an ordinary skilled artisan would be able to clearly envisage Applicant's claimed

compound from Deluca et al. since and the Y₁, Y₂, R₆ and R₆ genus are limited, thus very few combinations can be obtained. Please note that if one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Conclusions

Claim 22 is rejected. Claims 1-21 and 23-39 are withdrawn. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is (571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/
Examiner, Art Unit 1627

KRM

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627